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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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[illegible] AND ADLER
[illegible] CANDLE LANE
HOUSTON TX 77071

EXAMINER
SAYALA, C

ART UNIT	PAPER NUMBER
1761	7

DATE MAILED: 10/23/98

Pl ase find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/844731	Staley Brod
Examiner	**Group Art Unit**
Sayala	1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 8/20/98.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-18 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 1-18 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).____

☐ Interview Summary, PTO-413

☐ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other Seq Error Report

Office Action Summary

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

2. Claims 1-5, 6-7 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Cummins, Jr. (U.S. Patent 5019382).

See col. 4, lines 19-36, col. 5, lines 50-55, col. 6, lines 12-26, col. 13, and the claims. Such disclosure meets the claims.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

4. Claim 5 is rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382). The

disclosure is the same as above as discussed for claim 1. The patent does not disclose an alternate day dosing. However, it does show that a daily dosage is possible, as a single dosage or as divided and administered in a multiple daily dose regimen. The reference also teaches a staggered regimen of 1-3 days per week or month as an alternative to daily dosing. See col. 5, lines 50-55. With such a flexibility as taught by the reference, and since it is common knowledge in the art to employ such a regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc., it would have been obvious to one of ordinary skill in the art to adopt an alternate day dosing and administer IFN as shown by Cummins for MS.

5. Claims 1-~~20~~ 18 are rejected under 35 U.S.C. 103 as being unpatentable over Cummins, Jr. (U.S. Patent 5019382) in view of Shibutani et al. (Iyakuhin Kenkyu, vol. 18(4), pp. 571-82, 1987) and abstracts of WO 94/20122, Gross et al. and Giron et al.

The disclosure for the patent is as discussed above. The whole range of dosages claimed by the instant invention is not shown. However, the Shibutani abstract indicates that IFN toxicity studies with rats showed that it was tolerated well. Therefore it would have been obvious to one of ordinary skill in the art to administer dosages higher than that shown in the patent with the reasonable expectation that such doses would not produce toxicity

side-effects in humans. It would also have been obvious to employ such an alternate day dose regimen instead of continuous dosing, for a variety of reasons such as, toxicity, the condition of the patient, patient reaction and amelioration of the disease condition, etc. The references also do not disclose the prevention or treatment of diabetes. However, in view of the disclosure of the abstracts that show that it was already known in the art at the time the invention was made that interferon prevented the onset of diabetes, the subject matter as a whole would have been obvious to the person of ordinary skill in the art at the time the invention was filed.

6. Claims 1-7 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-7 of copending application Serial No. 08/631470. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

7. Claims 8-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending application Serial No. 08/631470 in view of the abstracts of WO 94/20122, Gross et al. and Giron et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of these claims would have been obvious in view of the abstracts that show that it was already known in the art at the time the invention was made that interferon prevented the onset of diabetes. [Filing date accorded to the claims

8, 12 and 16 reciting diabetes mellitus (prevention, etc.)is 4/15/96].

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

9. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). A computer readable form (CRF) of the sequence listing was submitted. However, the CRF could not be processed by the Scientific and Technical Information Center (STIC) for the reason(s) set forth on the attached CRF Diskette Problem Report. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached CRF Diskette Problem Report with the reply.

10. Applicant's arguments filed 8/20/98 have been fully considered but they are not persuasive.

On page 4 of the response applicant has criticized the Cummins reference for showing only one anecdotal report. He

argues that "this limited clinical data" cannot be considered enabling and therefore should be held "incredible". Enablement requires that the specification teach those in the art to make and use the invention without "undue experimentation". *In re Wands,* 858 F.2d 731, 737, 8 USPQ2d 140, 1404 (Fed. Cir. 1988). The specification and data therein is considered to be adequate to provide the skilled worker enough to practice the invention without "undue experimentation". A patent cannot be called "non-enabling" because applicant has produced data from 27 patients and 18 controls versus one example in the patent used.

As for amounts, the claims rejected do not contain the limitation that applicant has based his arguments on (SEE page 7, lines 1-2 of the response).

Applicant's discussion of Cummins' mode of administration at page 7 of the response is also not persuasive. There is nothing clearly distinguishable between "orally administering...such that the ...interferon is ingested after oral administration" and Cummins' mode. Applicant has argued at pages 7 and 8 that in his specification the interferon was fed through a needle inserted into the stomach and there was no oral or pharyngeal contact. There are no such limitations in the claims, however, and the relevance of this in view of the instantly claimed limitations is not clear.

Applicant also argues that there was only "brief" exposure of interferon to the oral mucosa in his method.

The claims herein do not recite anything to this end and there is no recitation to show such a "brief" exposure only.

Applicant's pointing out col. 5, lines 50-55 of Cummins is also not understood. The patent clearly teaches "Daily dosage of interferon....as a single dosage". Nowhere in any statute is there a requirement that only the preferred embodiment of the reference should be considered a teaching and the rest of the reference be ignored.

Both the traversal of the rejection over claim 5 and the declaration have been carefully reviewed and considered and the above discussions apply here too.

Applicant's traversal of the rejection of claims 1-20 at pages 12-14 is in error. Test for combining references is not what individual references themselves suggest but what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. *In re McLaughlin*, 170 USPQ 209 (CCPA 1970). Applicant has improperly criticized the references individually where the rejection is based upon the combined teachings of the references. *In re Merck., Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986); *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Unobviousness cannot be established by attacking references taken individually when rejection is based on a combination of references. *Ex parte Campbell* 172 USPQ 91 (BPA&I 1971). Note that Sobel was used only to show that the use of interferon for treating diabetes was known in the art. And Shibutani's abstract is